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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,434	01/13/2006	Cinderella Christina Gerhardt	f7683 (V)	6803

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EXAMINER	
BRADLEY, CHRISTINA	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/539,434	GERHARDT ET AL.	
	Examiner	Art Unit	
	Christina Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112 and 101

In light of the amendments to the claims the rejection of claims 1-7, 11 and 13 under 35 U.S.C. 112 and 101 has been withdrawn.

Claim Rejections - 35 USC § 102

Applicant's arguments, see pages 7 and 8, filed 10/12/2006, with respect to the rejection of claims 1, 3-10, 12 and 13 for being anticipated by Siemensma *et al.* (EP1112693), Reimer *et al.* (WO 01/37850) and Forse *et al.* (U.S. Patent No. 5,821,217) have been fully considered and are persuasive in light of the amendment to the claims. The rejection of these claims under 35 U.S.C. 102 has been withdrawn. However, a new grounds of rejection, necessitated by amendment, appears below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Callaghan *et al.* (WO 93/04593). O'Callaghan *et al.* teach infant formula comprising whey protein hydrolysate (page 6, line 28) with an average molecular weight of 1854.7 Daltons (the weighted average molecular weight based on the molecular weight distribution reported in Table 4).

Infant formula is administered orally to infants and provides a sustained feeling of energy and/or well-being following feeding. Regarding claims 2 and 11, the formula taught by O'Callaghan *et al.* comprises lactalbumin hydrolysate. Regarding claim 3, assuming a molecular weight of 16,000 Daltons for alpha-lactalbumin, the degree of hydrolysis of the whey protein in this composition is 11%. Regarding claims 4, 10 and 14, the whey protein hydrolysate is used at a concentration of 20.75% (see Table 3). Regarding claims 5, 7 and 9, the baby formula is an edible composition to be used as a meal replacement (the formula replaces breast milk) as part of dietary and weight management program (the administration of formula is designed to promote healthy weight gain and growth). Regarding claims 6, 8, 12 and 13, the baby formula is a liquid produced from a soluble powdered product and is a dairy based product, a beverage and a pre-packed meal product.

O'Callaghan *et al.* do not teach that the whey protein hydrolysate induces cellular release of glucagons-like-peptides and cholecystokinins and/or increases glucose uptake in target tissues. Because the chemical structure of the baby formula taught by O'Callaghan *et al.* is identical to the claimed invention, there is a reasonable expectation that the species would meet this additional functional limitation. The discovery and characterization of properties of a known material do not make it novel (see MPEP § 2112). Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference (see MPEP § 2112).

If the composition is physically the same, it must have the same functional properties. "Products of identical chemical composition can not have mutually exclusive properties." A

chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) See MPEP § 2112.01. Examiner cannot however determine whether or not the baby formula taught by O'Callaghan *et al.* inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerhardt *et al.* (U.S. Publication No. 20050238694). Gerhardt *et al.* teach whey protein hydrolysate (WPH) capable of inducing the cellular release of glucagon-like-peptides and cholecystokinins (paragraphs 0061-0062). The WPH has a weight average molecular weight in the range of from about 1000 Dalton to 12000 Daltons (paragraph 0067). Gerhardt *et al.* also teach methods for inducing satiety in a human or animal, for improving or controlling perception of body image, for controlling body weight, for controlling calorie intake and/or for helping adherence to a dietary plan, comprising administering an effective amount of the WPH (paragraph 0073).

Regarding claims 2 and 11, the WPH comprises hydrolysates of β-lactoglobulin or α-lactalbumin, or mixtures thereof (paragraph 0064). Regarding claim 3, the WPH has a degree of hydrolysis in the range of up to 20%, preferably of from 1 to 15%, more preferably of from 2 to 10%, such as 5 to 9% (paragraph 0066). Regarding claims 4, 10 and 14, the edible compositions comprise a total amount of from 0.1% to 80% by weight of the WPH based on the weight of the composition, preferably 0.1 to 40 or 50% wt, more preferably 0.5 or 1 to 30% wt (paragraph

0086). Regarding claims 5-7, 9 and 13, the edible composition is a meal replacement product that may be a ready to drink liquid, a liquid produced from a soluble powdered product, a soup, a dessert, a bar, a cereal based or pasta based or noodle based product, or, a soluble or dispersible powdered product (paragraph 0084). Regarding claims 8 and 12, the edible composition of WPH may be dairy based products (such as milk based products and drinks), soy based products, breads and cereal based products (including pasta and cereal bars), cakes, biscuits, spreads, oil-in-water emulsions (such as dressings and mayonnaise), ice creams, desserts, soups, powdered soup concentrates, sauces, powdered sauce concentrates, beverages, sport drinks, health bars, fruit juices, confectionery, snack foods, ready-to-eat meal products, pre-packed meal products, and dried meal products (paragraph 0082).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/519,657. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 16 of copending Application No. 10/519,657 is drawn to a method for inducing satiety comprising administering to a human by means of an edible composition, an effective amount of a whey protein hydrolysate which is capable of inducing the cellular release of glucagon-like peptides and cholecystokinins. The claim does not require that the average molecular weight of the WPH be in the range of 1000-12000 Daltons. The specification of copending Application No. 10/519,657 states that the preferred WPH has a weight average molecular weight in the range of from about 1000-12000 Daltons (paragraph 0067). Therefore, it would have been obvious to the skilled artisan to use WPH with an average molecular weight of 1000-12000 Daltons.

Regarding claims 2 and 11, claim 3 of copending Application No. 10/519,657 requires that the WPH comprise hydrolysates of β-lactoglobulin or α-lactalbumin, or a mixture thereof. Regarding claim 3, claim 5 of copending Application No. 10/519,657 requires that the WPH has a degree of hydrolysis in the range of 1 to 20. Regarding claims 4, 10 and 14, claim 18 of

copending Application No. 10/519,657 requires that the edible compositions comprise a total amount of from 0.1% to 80% by weight of the WPH based on the weight of the composition. Regarding claims 5-9, 12 and 13, claim 9 of copending Application No. 10/519,657 requires that the edible composition is a meal replacement product that may be a ready to drink liquid, a liquid produced from a soluble powdered product, a soup, a dessert, a bar, a cereal based or pasta based or noodle based product, or, a soluble or dispersible powdered product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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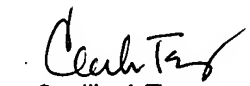

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